

Remarks

Claim 1 has been amended. Claims 1, 3-5, 9, 11-13, 15, 17, 21-23, 28, and 31 remain in the application. No new searching is believed to be required as a result of the minor amendment to Claim 1. As such, reconsideration and allowance of these claims as now presented is respectfully requested.

Rejection of Claims Under 35 U.S.C. §103

Claims 1, 3-5, 10-12, 17, 23, and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. (GB 2,202,145) in view of Jacobs et al. (U.S. 5,939,085) and Sang et al. (U.S. 6,143,310). Totten et al. '145 generally disclose dermatological compositions having nedocromil sodium and ethoxylated mixtures of cetyl and stearyl alcohols. The Jacobs et al. '085 patent is generally directed to skin smoothing compositions, including surfactants such as disodium cocoamphodiacetate. Sang et al. '310 disclose a cosmetic composition, and identify PPG-5 ceteth-20 as a suitable solubilizing agent.

I. The Cited Prior Art, Whether Taken Alone Or In Combination, Fails To Teach Or Suggest The Presently Claimed Composition.

The Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time of the

invention to add the disodium cocoamphodiacetate of Jacobs et al. '085 to the composition of Totten et al. '145. The Examiner rationalizes this assertion by stating that the motivation behind combining such references lies in the fact that both such references are directed to oil-in-water emulsions, and Jacobs et al. '085 describes the disodium cocoamphodiacetate surfactant as imparting smoothness to the skin and emulsion stability. Applicant respectfully submits, however, that the reasons stated by the Examiner are not tantamount to an incentive to combine the cited references to achieve the compositions of the present invention. Specifically, the surfactant characteristics described in Jacobs et al. '085 are not wont for lacking in Totten et al. '145, nor would such characteristics lead to the unexpected results of the present invention. In other words, one of ordinary skill in the art, upon the reading Totten et al. '145 patent, would not search out the components described in Jacobs et al. '085 for the respective characteristics thereof, as no such need is described in the Totten et al. '145 patent. Accordingly, no incentive exists for one of ordinary skill in the art to combine Jacobs et al. '085 with Totten et al. '145.

Moreover, the cited references fail to provide an incentive to combine respective components into the

presently claimed compositions. Namely, Jacobs et al. '085 describe a surfactant in an emulsion, but does not suggest combining such a surfactant with an alkoxyated cetyl alcohol. Similarly, Sang et al. '310 describes an alkoxyated cetyl alcohol in an emulsion, but does not suggest combining such an alkoxyated cetyl alcohol with an amphoteric surfactant, as is presently claimed. Applicant respectfully submits that the cited prior art nowhere teaches or suggests the combinations of the presently claimed invention and further provides no incentive to combine individual components into the presently claimed compositions. In deriving the prima facie case for obviousness, one "cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention", but rather must "show specific teaching or suggestion in the references to support their use in the particular claimed combination" Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 887 (Fed. Cir. 1988). Here, no specific teaching or suggestion is found in the references to combine an amphoteric surfactant with an alkoxyated cetyl alcohol in a composition containing a polar drug. Accordingly, Applicant respectfully submits that the

Examiner's assertion of obviousness is unsupported by the cited prior art.

**II. The Claimed Compositions Introduced  
Unexpected Results.**

In addition to the above, the cited references whether taken alone or in combination fail to teach or suggest the unexpected results of the present invention, particularly an effective topical treatment of skin maladies. According to the Declarations filed May 19, 2003, the claimed combination of an amphoteric surfactant and an alkoxyated cetyl alcohol provides the unexpected result of enhancing the transdermal transmission of the polar drug in the claimed compositions.

In the present Office Action (Paper No. 20), the Examiner directs the Applicant to demonstrate unexpected results over the closest prior art, Totten et al. '145. The enclosed Declaration of Alan Edwards both describes the stark effectiveness differences between that of the claimed compositions and of Totten et al. '145, and includes Exhibits A and B which represent statistical and practical comparisons between Totten et al. '145 and the presently claimed compositions. In short, the enclosed Declaration with Exhibits A and B demonstrate that the claimed compositions are clinically effective while those of Totten

et al. '145 fail. As stated in *Van Bever et al.* Exhibit B) describing the compositions of Totten et al. '145, "4% nedocromil sodium cream, applied during four weeks, twice daily, has no advantage over placebo in the treatment of patient's (older children and adults) with atopic dermatitis". By contrast, Exhibit A, which lists clinical results of the claimed compositions, indicates a high occurrence of beneficial results.

The Examiner further states that the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. Indeed, the teaching of Totten et al. '145 (*Van Bever et al.*) is that a dermal application of nedocromil sodium in an oil-in-water emulsion is utterly ineffective against atopic dermatitis. Nowhere does the cited prior art, whether taken alone or in combination, suggest that the combination of an alkoxylated cetyl alcohol with an amphoteric surfactant in an oil-in-water emulsion having nedocromil sodium would result in an effective dermal composition against atopic dermatitis. Thus, the differences in the results between Totten et al. '145 and that of the presently claimed compositions are in fact unexpected and unobvious.

Moreover, the differences in the results evidenced in Exhibits A and B accompanying the Declaration of Alan Edwards enclosed herewith are of both statistical and practical significance. Namely, the Totten et al. '145 composition has no advantage over placebo in the treatment of patients with atopic dermatitis. Conversely, and as described in the "notes" section of Exhibit A describing the results of the presently claimed compositions, 39 of 45 named patients showed improvement after using the topical compositions of the present invention. Accordingly, the differences in the results have an overwhelmingly statistical significance. As an obvious consequence of having about 87% in the treatment efficacy of the compositions of the present invention, many patients may potentially be relieved from painful and irritating symptoms as a direct result of the utilization of the compositions of the present invention. Clearly, the differences in results shown are of a substantial practical significance.

The Examiner additionally states that the unexpected benefits must be of a scope reasonably commensurate with the scope of the subject matter claimed. The present claims recite an aqueous phase and oil phase composition having an amphoteric surfactant, an alkoxylated cetyl

alcohol, and a polar drug selected from the group consisting of sodium cromoglycate and nedocromil sodium, with the composition being adapted to provide transdermal transmission of the polar drug. The unexpected results specifically identified in Exhibit A of the Alan Edwards Declaration are the direct fruit from the claimed compositions. Such results are unexpected, in that there is no reason to believe from the cited prior art that the claimed composition would provide the beneficial clinical results set forth in Exhibit A. In other words, there is no suggestion from the cited prior art that the combination of an alkoxylated cetyl alcohol with an amphoteric surfactant in an oil-in-water emulsion having a polar drug would provide an effective topical remedy against skin maladies.

The Examiner repeatedly argues that the claimed compositions are an obvious derivation given the cited references. The Applicant respectfully queries that if such components were so obvious to combine, why would it have not been accomplished prior to the date of the present invention? As stated on page 5-240 of Chisum on Patents, "[i]f an invention is advantageous but obvious, it is likely that persons in the art would have been led by normal economic incentive to develop it sooner". As stated

in the enclosed Declaration by Alan Edwards, the compositions of the present invention are unique and novel to the Applicant. It therefore follows that the creation of the unique combination of components represented in the claimed compositions are unobvious and patentable over the cited prior art, whether taken alone or in combination.

**III. The Claimed Compositions Satisfy a Long-Felt Need In The Art for the development of an acceptable topical vehicle which allows adequate skin transmission of a polar drug, and particularly sodium cromoglycate and nedocromil sodium.**

The Examiner states that to establish the satisfaction of a long felt need, the need must have been a persistent one that was recognized by those of ordinary skill in the art, and must not have been satisfied by another before the invention by Applicant. Further, the invention must in fact satisfy the long felt need. Here, the need was in fact a persistent one, in that various skin maladies have long been present. Treatments for such skin maladies have therefore long been desired, and particularly topical treatments which are relatively inexpensive and easily self administered. Those of ordinary skill in the art certainly recognize that the need for treating skin maladies has been a persistent one. Moreover, and as stated in the enclosed Declaration by Alan Edwards, the long felt need had not been satisfied by another before the present invention.



The composition of Totten et al. '145, for example, attempted but failed to provide an effective topical treatment for various skin maladies, including atopic dermatitis. Finally, the presently claimed compositions in fact satisfy the long felt need, as evidenced by Exhibit A of the Alan Edwards Declaration enclosed herewith. Indeed, an effective topical treatment for various skin maladies is obtained via the compositions of the present invention. Thus, the present invention satisfies a long felt need that is widely recognized by those of ordinary skill in the art.

For the foregoing reasons, claims 1, 3-5, 10-12, 17, 23, and 28 as well as all other pending claims, are believed to be unobvious and patentable over the cited prior art, and particularly over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310. The claim rejections based thereon should accordingly be withdrawn.

Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085 and Sang et al. '310, and further in view of Dener et al. (WO 98/04537) and Haider (1979). The references of Dener et al. '537 and Haider, whether taken alone or in combination, fail to cure the defects of the cited references discussed above. Therefore, the claim rejections based thereon should accordingly be withdrawn.

Claims 15 and 21 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085. The combination of Totten et al. '145 and Jacobs et al. '085, as discussed above, fail to teach or suggest the presently claimed compositions of the present invention, and particularly those embodied in claims 15 and 21. Accordingly, The claim rejections based thereon should be withdrawn.

Claim 31 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Sang et al. '310. For the reasons stated above, the cited references, whether taken alone or in combination, fail to teach or suggest the claimed combinations of the present invention. Therefore, the claim rejections based thereon should be withdrawn.

Claim 22 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Totten et al. '145 in view of Jacobs et al. '085, and further in view of Dener et al. '537 and Haider. For the reasons stated above, the cited references, whether taken alone or in combination, fail to teach or suggest the compositions of the claimed invention. Accordingly, The claim rejections based thereon should be withdrawn.

For the foregoing reasons, the claims as now presented are believed to be unobvious and patentable over the cited prior art, whether taken alone or in combination. Applicant therefore submits that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

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